

LACHMAN CONSULTANT SERVICES, INC.
CONSULTANTS TO THE PHARMACEUTICAL AND ALLIED INDUSTRIES

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0667 '00 SEP 29 19:32

OVERNIGHT COURIER 9/28/00

September 28, 2000

Dockets Management Branch
Food and Drug Administration (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir or Madam:

This petition is submitted in quadruplicate pursuant to 21 CFR 10.30 and in accordance with the regulations at 21 CFR 314.161, requesting the Commissioner of the Food and Drug Administration to provide a determination whether a listed drug has been voluntarily withdrawn for safety or effectiveness reasons, as outlined below.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration determine whether Neoral® Soft Gelatin Capsules (Cyclosporine Capsules for microemulsion) 50 mg, (NDA No. N50715), by Novartis Pharmaceuticals Corp., have been voluntarily withdrawn or withheld from sale for safety or efficacy reasons.

B. Statement of Grounds

Neoral® Soft Gelatin Capsules (Cyclosporine Capsules for microemulsion) 50 mg, (NDA No. N50715), by Novartis Pharmaceuticals Corp., are not available for sale in the marketplace. Because there is no current commercial distribution of this drug product, it is requested that the FDA determine whether Novartis' decision not to market Neoral® Soft Gelatin Capsules (Cyclosporine Capsules for microemulsion) 50 mg, was for reasons for safety or effectiveness. Please note, that the current edition of the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("The Orange Book") does not list Neoral® Soft Gelatin Capsules (Cyclosporine Capsules for microemulsion) 50 mg, in the Discontinued Drug Product List section.

00P-1548

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C. Environmental Impact

A claim for categorical exclusion of the requirements for an environmental assessment is made pursuant to 21 CFR 25.31.

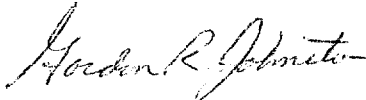
D. Economic Impact

Pursuant to 21 CFR 10.30(b), economic impact information is submitted only when requested by the Commissioner. This information will be promptly provided, if so requested.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that includes representative data and information known to the petitioner, which are unfavorable to the petition.

Respectfully submitted,



Gordon R. Johnston

GJ/pk

36K0272

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